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(to be used for all correspondence after initial filing)

Application Number	10/787,385
Filing Date	02/26/2004
First Named Inventor	Steven C. Quay
Art Unit	1623
Examiner Name	
Total Number of Pages in This Submission	6
Attorney Docket Number	03-02US

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement Form 1449, 7 pages <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance communication to (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input checked="" type="checkbox"/> Information Disclosure Statement for 37 CFR <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Nastech Pharmaceutical Company Inc.		
Signature			
Printed name	Paul G. Lunn		
Date	January 14, 2005	Reg. No.	32,743

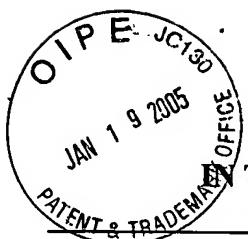
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Typed or printed name	Jeffrey L. Granger	Date	January 14, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Quay et al.

Serial No.: 10/787,385

Filed: 2/26/2004

Title: CYANOCOBALAMIN LOW
VISCOSITY AQUEOUS
FORMULATIONS FOR
INTRANASAL DELIVERY

Group Art Unit: 1623

Attorney Docket No.: 03-02US

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted:

- under 37 CFR 1.97(b), or
 - (Within three months of filing national application; or date of entry of international application; or **before mailing date of first office action** on the merits; whichever occurs last)
- under 37 CFR 1.97(c) together with either a:
 - Statement under 37 CFR 1.97(e), or
 - a \$180.00 fee under 37 CFR 1.17(p), or
 - (After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- under 37 CFR 1.97(d) together with a:
 - Statement under 37 CFR 1.97(e), and
 - a \$180.00 fee set forth in 37 CFR 1.17(p).
 - (Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which

applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,



Paul G. Lunn
Attorney/Agent for Applicant(s)
Reg. No. 32743

Date: January 14, 2005

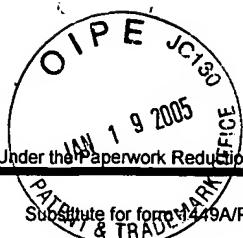
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Date of Deposit: January 14, 2005

Typed Name: Jeffrey L. Granger

Signature: Jeffrey L. Granger



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number	10/787,385
Filing Date	2/26/2004
First Named Inventor	Quay et al.
Art Unit	1623
Examiner Name	

Attorney Docket Number 03-02US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Issued Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 2,703,302	03-01-1955	Merck & Co. Inc.	
		US- 2,703,303	03-01-1955	Merck & Co., Inc.	
		US- 2,746,796	05-22-1956	The Pharma-Craft Corporation	
		US- 2,914,222	11-24-1959	Philip Meshberg	
		US- 3,000,793	09-19-1961	Merck & Co., Inc.	
		US- 2,951,017	08-30-1960	The Distillers Company Limited	
		US- 3,057,851	10-09-1962	Armour Pharmaceutical	
		US- 3,018,225	01-23-1962	Merck & Co., Inc.	
		US- 3,120,509	02-04-1964	Hoffmann-La Roche Inc.	
		US- 3,282,781	11-01-1966	Merck & Co., Inc.	
		US- 3,548,057	12-15-1970	Merck & Co., Inc.	
		US- 3,577,537	05-04-1971	Merck & Co., Inc	
		US- 3,584,115	06-08-1971	Arthur I. Gebhart & Angelo T. Bonduris	
		US- 3,957,966	05-18-1976	GAF Corporation	
		US- 4,174,295	11-13-1979	Montedison S.p.A.	
		US- 4,523,341	06-25-1985	Mayor Pharmaceutical Laboratories	
		US- 4,724,231	02-09-1988	Nastech Pharmaceutical, Inc.	
		US- 5,801,161	09-01-1998	Merkus, Franciscus	
		US- 5,797,390	08-25-1998	McSoley, Thomas E.	
		US- 5,925,625	07-20-1999	Merkus, Francicus	
		US- 6,665,421	12-16-2003	Image Therm Engineering, Inc.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		EP 0131315 A2	02-15-1984	Istituto De Angeli		
		EP 0130550 A2	06-27-1984	Instermedical GmbH		
		PCT WO 86/05988 (International Application Number PCT/US86/00793)	10-23-1986 Publication Date	Nastech Pharmaceutical Company, Inc.		
		PCT WO 86-05987 (International Application Number PCT/US86/00665)	10-23-1986 Publication Date	Nastech Pharmaceutical Company, Inc.		

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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Complete if Known	
Application Number	10/787,385
Filing Date	2/26/2004
First Named Inventor	Quay et al.
Art Unit	1623
Examiner Name	

Attorney Docket Number 03-02US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		RAYMOND W. MONTO, JOHN W. REBUCK, MICHAEL BRENNAN, Crystalline B ¹² Inhalation Therapy in Pernicious Anemia, The American Journal of the Medical Sciences, 2-1953, Pages 113-119, Publisher: Division of Hematology and Department of Laboratories, The Henry Ford Hospital, Detroit, Michigan Published in: Detroit, MI, US	
		RAYMOND W. MONTO, JOHN W. REBUCK, Nasal Instillation and Inhalation of Crystalline Vitamin B ¹² in Pernicious Anemia, A.M.A. Archives of Internal Medicine, Volume 93, 1954, From the Division of Hematology (Dr. Monto) and the Department of Laboratories (Dr. Rebuck), The Henry Ford Hospital. Pages 219-230. Detroit, MI, US.	
		RAYMOND W. MONTO, JOHN W. REBUCK, Observations on the Mechanism of Intranasal Absorption of Vitamin B ¹² in Pernicious Anemia. Blood, Volume 10, 1955, pages 1151-1155, From the Division of Hematology (Dr. Monto) and the Department of Laboratories (Dr. Rebuck), The Henry Ford Hospital. Detroit, MI, US.	
		A. KILLANDER AND I. WERNER, Studies on Maintenance Treatment of Pernicious Anaemia, Vitamin B ¹² and Intrinsic Factor Europaisches Symposium Hamburg, 1961, Pages 663-667, Ed. H.c. Heinrich, Enke, Stuttgart, Department of Pediatrics and Internal Medicine, Akademiska, Sjukhuset, Uppsala, Sweden	
		N.K. SHINTON AND A.K. SINGH, Vitamin B ¹² absorption by inhalation, Chemical Abstracts, Volume 66, Number 15, Coden: Chaba8, The American Chemical Society, 4/10/1967, Page 6024, Abstract 64246(e) Northhampton Sts, Easton, PA, US.	
		N.K. SHINTON AND A.K. SINGH, Vitamin B ¹² Absorption by Inhalation, Brit. J. Haemat, 1967, 13. Pages 75-79, Department of Haematology, Coventry and Warwickshire Hospital, Coventry	
		FOREST LABORATORIES, INC., Long Acting oral carrier, Chemical Abstracts, Volume 77, Year 1972, Page 263, Abstract 105623(y)	
		SALLY MATHISON, RAKESH NAGILLA, AND UDAY B. KOMPELLA, Nasal Route for Direct delivery of Solutes to the Central Nervous System: Fact or Fiction? Journal of Drug Targeting, 1998, Volume 5, No. 6, pages 415-441 Department of Pharmacal Science, Department of Chemistry, Auburn University, Auburn, AL US	
		ANTHONY J. CUTIE AND JOHN J. SCIARRA, Intranasal Pharmaceutical Aerosols, Aerosol Age, The International authority in Spray Packaging, Aerosol Age Magazine, 10/1982, Pages 1-4	
		R.K. CHANDRA, GLORIA HERESI, AND G. WOODFORD, Double-blind controlled crossover trial of 4% intranasal sodium cromoglycate solution in patients with seasonal allergic rhinitis, Annals of Allergy, 09/1982, Volume 49, From the Department of Pediatrics, Memorial University of Newfoundland, Janeway Child Health Center and Health Sciences Center, St. John's , Newfoundland, Canada	

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<i>Art Unit</i>	1623
<i>Examiner Name</i>	

Attorney Docket Number 03-02US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Edited by JAMES E.F. REYNOLDS, Cyanocobalamin, Martindale, The Extra Pharmacopoeia, 1982, Abstract 7853-d, and Page 1645, Cyanocobalamin Injection, 28 th Edition, Published by direction of the Council of The Pharmaceutical Society of Great Britain and prepared in the Society's Department of Pharmaceutical Sciences, The Pharmaceutical Press, London, UK	
		CHENG DER YU, RICHARD JONES, JIM WRIGHT, AND MAIDA HENESIAN, Characterization of dose delivery and spray pattern of a metered-dose flunisolide nasal spray, Drug development and Industrial Pharmacy, 1983, 9(3), Pages 473-483, Institute of Pharmaceutical Sciences, Syntex Research, Palo Alto, CA Marcel Dekker, Inc., US	
		ANWAR A. HUSSAIN, YUKIHIKO ARAMAKI, Studies on the Intranasal Absorption of vitamin B ¹² in the Rat, Final Report, 12/1984, University of Kentucky, College of Pharmacy, Lexington, KY, US	
		Valois, Pumps for Pharmacy, Year Unknown (product brochure)	
		JOHN J. SIARRA, Aerosols, Chapter 92, Year Unknown, Pages 1614-1621, Arnold & Marie Schwartz Collet of Pharmacy and Health Sciences, Long Island University, Brooklyn, NY, US	
		T.Q.NIJST, R.A. WEVERS, H.C. SCHOONDERWALDT, O.R. HOMMES, A.F.J. DE HAAN, Vitamin B12 and folate concentrations in serum and cerebrospinal fluid of neurological patients with special reference to multiple sclerosis and dementia, Journal of Neurology, Neurosurgery, and Psychiatry, Year 1990; 53, Page 951-954	
		GARCIA-ARIETA, A.; TORRADO-SANTIAGO, S.; GOYA, L.; TORRADO, J. J., Spray-dried powders as nasal absorption enhancers of cyanocobalamin, Biol.Pharm.Bull, date- 2001, Volume 24, issue- 12, Pages 1411-1416, Pharmaceutical Society of Japan	
		U.S. DEPARTMENT OF HEALTH AND HUMANS SERVICES, Guidance for Industry, Nasal spray and inhalation solution, suspension, and spray drug products-chemistry, manufacturing, and controls documentation, 07/2002, Pages 1-44, Food and Drug Administration, Center for Drug Evaluation and Research, Rockville, MD, US	

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